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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,187	03/18/2004	Thomas Christoph	029310.53299US	5120
23911 7590 12/26/2007 CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			EXAMINER KUDLA, JOSEPH S	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,187

Applicant(s)

CHRISTOPH, THOMAS

Examiner

Joseph S. Kudla

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,39-41,48-51,54-57 and 71-73 is/are pending in the application.
- 4a) Of the above claim(s) 38,44-47,52,53 and 58-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,39-41,48-51,54-57 and 71-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/30/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. This application claims the benefits as a continuation of PCT Application No. PCT/EP02/10460 filed on September 18, 2002 and Foreign Priority Application No. DE 101 46 275.1 filed September 18, 2001. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d), a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Priority is **not** acknowledged.

Appropriate action is required.

Election/Restrictions

2. Applicant's election **without** traverse of claims 37-73 in the reply filed 9/27/07 is acknowledged. Claims 1-36 are cancelled without prejudice. Claims 38, 42-47, 52-53 and 58-70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions/species, there being no allowable generic or linking claim. Applicant elected the species (+)-(2R, 3R)-1-dimethylamino-3-(3-methylphenyl)-2-methylpentan-3-ol without traverse. The Examiner appreciates the election of species for the anti-muscarinic agent, oxybutynin, however; the election of

species for the anti-muscarinic agent was not required in the Restriction/Election correspondence dated 9/11/2007 and will not be required.

Oath/Declaration

3 The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

The title of the invention for application 10/803187 is not reflected in the declaration presented.

Appropriate action is required.

Specification

4. The disclosure is objected to for the following informalities: The parenthetical around the word "LAAM" is encased within the parenthetical "(1- α -acetylmethadol (LAAM))" on page 6, line 6 and page 29, line 1; however, the abbreviation LAAM appears to represent the capitalized bold letters in the compound name Levomethadyl-Acetate-(1- α -Acetyl**M**ethadol). If this is the case, then the compound should be written levomethadyl-acetate-(1- α -acetylmethadol) (LAAM).

Claim Objections

5. Claim 37 is objected to for the following informalities: The parenthetical around the word "LAAM" is encased within the parenthetical "(1- α -acetylmethadol (LAAM))," however; the abbreviation LAAM appears to represent the capitalized bold letters in the

compound name Levomethadyl-Acetate-(1- α -AcetylMethadol). If this is the case, then the compound should be written levomethadyl-acetate-(1- α -acetylmethadol) (LAAM).

6. Claim 37 is objected to for the following informalities: The parenthetical around the word "LAAM", "merperidine" and "heroin" excludes the abbreviations. If applicant seeks inclusion of the abbreviations "LAAM", "merperidine" and "heroin", the parentheses should be removed. If the abbreviations "LAAM", "merperidine" and "heroin" are meant as examples of the compound levomethadyl-acetate-(1- α -acetylmethadol), pethidine and diacetylmorphine, respectively, then the abbreviations "LAAM", "merperidine" and "heroin" should be cancelled as well due to the disclosure on pages 5-6, paragraph 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 37, 39-41, 48-51, 54-57 and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christoph et al (U.S. PG Publication US 2004/0034105) in view of Andersson et al ("The pharmacological treatment of urinary incontinence," 1999, British Journal of Urology International, 84:923-947 and cited by Applicant).

Christoph et al. teach the use of 1-phenyl-3-dimethylaminopropane compounds for treating increased urinary incontinence (Abstract). A specie of the generic structure of the 1-phenyl-3-dimethylaminopropane compounds described on page 1, column 2 paragraph 10, to page 2, column 1, paragraph 24 includes (+)-(2R,3R)-1-dimethylamino-3-(3-methylphenyl)-2-methylpentan-3-ol (page 3, column 2, paragraph 59). Christoph et al. also teach the compounds are in the form of free bases (page 2, column 1, paragraph 2), or in the form of a diastereomer (pure or racemic), or as an enantiomer (pure or racemic) (page 3, column 1, paragraph 54 to column 2, paragraph 56). The limitations of Instant claim 48 are taught on page 2, column 2, paragraph 32 to page 3, column 1, paragraph 52. Christoph et al. teach pharmaceutical compositions on page 4, column 2, paragraph 92.

Christoph et al. do not teach the use of an anti-muscarinic agent for the treatment of urinary incontinence nor provide motivation to form a composition of the 1-phenyl-3-dimethylaminopropane compound.

Andersson et al. disclose pharmaceutical substances that are known to treat urinary incontinence (Title) and include anti-muscarinic agents such as atropine, propantheline, emepronium, trospium, tolterodine, darifenacin, oxybutynin and propiverine (page 924 and 925, table 2).

It would have been obvious to one of ordinary skill in the art to combine the two therapies for urinary incontinence because both analgesic compounds such as 1-phenyl-3-dimethylaminopropane compounds and the muscarinic compounds as described *supra* are known to treat urinary continence. "It is *prima facie* obvious to

combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

Therefore, the teachings of Christoph et al in view of Anderson et al render the claimed invention obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am-5pm EST.

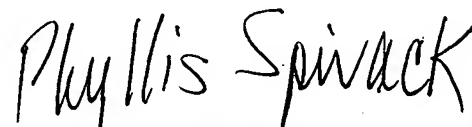
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


JK


PHYLLIS SPIVACK
PRIMARY EXAMINER
12/19/07